Hospital Experience with Bacterial Testing of Platelet Concentrates - Operations and Economics

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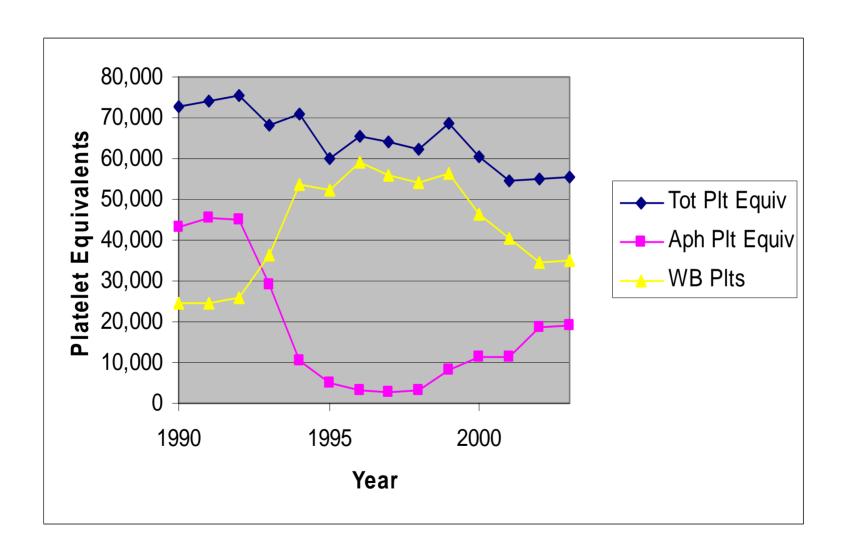
Fairview University Medical Center 2002

- 972 staffed beds
- 36,191 admissions / year
- 20,612 surgical cases, 3,512 in pediatrics
- 609 adult organ transplants, 33 in pediatrics
- 183 adult Marrow transplants, 55 in pediatrics

<u>Transfusion Activity – FUMC</u> 2003

Leukoreduced red cells	18,588
Platelet equivalents (LR)	54,152
Frozen Plasma	11,489
Cryoprecipitate	4,264

Platelet Usage Strategy - FUMC



<u>Transfusion Reactions – Bacteria</u> <u>Contaminated Blood Components at</u> <u>FUMC</u>

Fatalities

- 1989	RBC	Yersinia enterocolitica

– 1999 Platelet Pool Serratia marcescens

Nonfatal Reactions

-5/8/01	Platelet Pool	Bacillus cereus
- $J/U/U1$		Dacillus celeur

9/9/02 Platelet Pool Coag neg staph

- 7/9/03 Platelet Pool Coag neg staph

- 8/8/03 Plateletpheresis Coag neg staph

– 10/9/03 Plateletpheresis Staph aureus

– 1/27/04 Platelet Pool Staph epidermidis

The New Standard - Challenges

- What test should we use?
- How much will it cost?
- Change in practice? All apheresis (vs. WB) platelets?
- Other?

Timeline at FUMC

- July '03 began to define our approach.
- August '03 initial investigations.
 - "heads up" to management. Money needed.
 - Demonstrations of technology
- September '03 Specific outline including reviews of literature, consultations, technology assessment, cost impact.
- AABB Monitor Bulletins, Annual Meeting. Given the Standard, AABB did a good job of giving guidance.
- December '03 Final decision on technology, validation plan, implementation plan.
- March 1, 2004 implementation.

Approach/Rationale to Guide our Actions

- We will meet the Standard.
 - -On time. With an "accepted" test.
- Collaborate with our supplier (ARC in St Paul).
- Prudent to be a late adopter.
- Minimize the operational and ecomomic impact.

Implications of Our Approach

- Maintain current apheresis/WB platelet mix.
- Keep testing simple monitor technology.
- Observe supplier's efforts in testing and improvements in collection technique (diversion).
- Monitor regulatory policy on prestorage pooling of platelets derived from WB (currently prohibited).

Ecomomic Impact

How bad is it?

\$1.5 million over expected expenses! Wait-a-minute, that's 42% more!

Are there options?

Economic Impact – Model Study

- 1000 Apheresis platelet concentrates.
- 47,000 WB platelet concentrates (LR).
- Five WB platelets are equivalent to one Aph platelet.
- Estimated cost to test for bacteria \$30/ test.

Economic Impact – Model Study

Platelet Supply Strategy	Cost (millions)
Current Product Mix @ current prices	
1000 Apheresis, 47000 LR Plt Conc	\$3.54
Current Prod Mix	
Add Bact test at \$30/unit	\$4.98
Convert to All Apheresis + Bact test	
10400 Apheresis	\$5.08
Current Product Mix	
Bact test Sterile Connected Plt pools	\$3.99
Current prod Mix	
LR & Bact test Sterile Connected Plt pools	\$3.50

Table: Comparison of platelet supply strategy and cost.

Selected Option

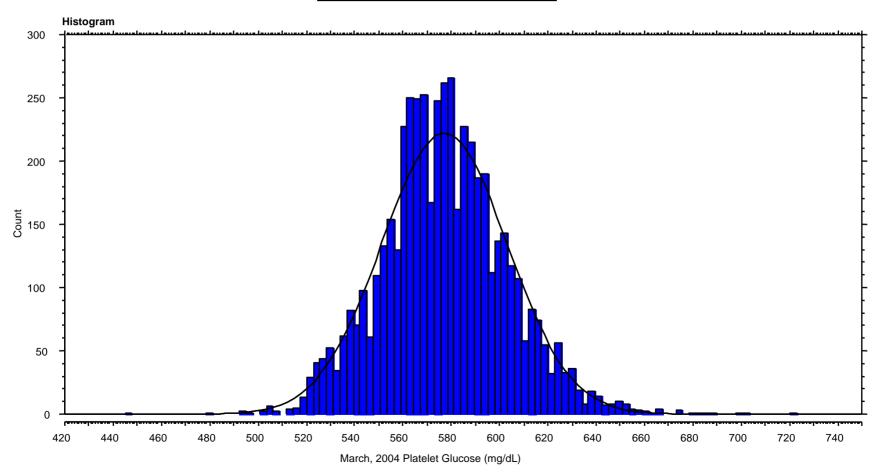
- Test each WB platelet ourselves Why?
 - Aph vs. WB plts no change in practice.
 - No change for supplier adequacy of supply.
 - \$\$ we think we can test for less than \$30/test.
- Use bact tested apheresis platelets from supplier we don't use many and it is easier than establishing additional test criteria.
 - Added cost of about \$30,000 per year.

Selected Option - Test WB Plts

- Test each WB platelet ourselves.
- Process
 - Screen using Glucometer (SureStep ®Flexx Meter).
 - Eight Hours arbitrary, not well established.
 - Cutoff < 520 mg/dl. Units failing screen are not used.
 - Reflex testing on Radiometer ABL TM725 Series
 Analyzer (glucose, pH, lactate). pH < 6.2 reported to supplier.
 - Gram Stain and Culture. Any pos reported to supplier.
 - Estimated cost about \$3 per test (direct cost).
- Total added expense of about \$150,000 (but redundant testing adds another \$60,000).

Results - Glucose Levels in Whole Blood Platelets

March 1-28, 2004



Results: March 1-28, 2004

WB Plts received	3425
WB plts tested	5197
Platelet tests with glucose ≤ 520	38
Platelets with pH < 6.2	2
Platelets with Pos Culture or G-stain	0

Results: March 1-28, 2004

- We have not experienced shortages.
 - But we did not change to all Aph platelets.
- Operations can be improved.
 - We didn't appreciate the redundant testing driven by the 8 hour period set for test validity.
 - Can we lower our cutoff?
 - Hired an additional FTE.
 - Improve computer interface.

What is needed?

- Better testing that includes G+ and G- organisms.
 - Automated, Blood Center friendly.
 - Sensitive, specific, etc.
- An objective assessment of pooled stored WB platelets.
 - Leukocyte reduction filtration
 - Bacterial testing

Economic Benefit of Prestorage Pooling

Platelet Supply Strategy	Cost (millions)
Current Product Mix @ current prices 1000 Apheresis, 47000 LR Plt Conc – No Bact Test	\$3.54
Current prod Mix – Prestore WB Pools LR & Bact test Sterile Connected Plt pools	\$3.50

It is time to consider pooling whole-blood PLTS before WBC reduction, bacterial testing, and storage.